DETAILED ACTION

Status of the Claims

Claims 1-11 are pending in the present application and are examined herein on the merits for patentability. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 20 October 2005, 27 January 2006 and 16 November 2006 were filed before the mailing of a first Office action on the merits. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. All of the documents listed in the IDS filed 16 November 2006 were previously cited in the IDS filed 20 October 2005. Therefore, the documents have been lined through. Also, the documents listed under Cite No. BA-BD in the IDS filed 27 January 2006 were previously cited in the IDS filed 20 October 2005. Therefore, the documents have been lined through.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ninomiya et al. (US 5,266,598).

Ninomiya et al. disclose skin disinfectant compositions comprising 0.5-10 w/v% chlorhexidine digluconate and 5-25 w/v% polyoxyethylene alkyl ether (Abstract), wherein the polyoxyethylene alkyl ether can be obtained by conducting an addition reaction of long-chain fatty alcohols (8-20 carbon atoms, for example octyl, nonyl, oleyl, lauryl, myristyl, cetyl, stearyl and the like, and alkyl also includes alkenyl) with about 5-100 mole of ethylene oxide (col. 2, ln. 21-27). The ingredients are dissolved in an aqueous medium, usually water, but may also comprise up to 10 w/v% of lower alcohols, such as ethanol and isopropanol, wherein the alcohol will enhance the stability of the composition; and gluconic acid is added to adjust to a pH of 5.5-7.0 (col. 2, ln. 56-65). An appropriate amount of the composition, for example 2-5 ml, is applied to skin that has been wetted with water (i.e., dilution), followed by washing and then rinsing away with running water (col. 1, ln. 65 through col. 2, ln. 3).

Ninomiya et al. further disclose a specific example comprising 4 w/v% chlorhexidine digluconate, 5 w/v% polyoxyethylene oleyl ether (30 E.O.), 5 w/v% polyoxyethylene cetyl ether (40 E.O.), 1 w/v% gluconic acid, 5.5 w/v% ethanol and water (Example 1); and a specific example comprising 4 w/v% chlorhexidine digluconate, 22 w/v% polyoxyethylene nonylphenyl ether (9 E.O.), 1 w/v% gluconic acid, 5.5 w/v% ethanol and water (Example 2). See also claims 1-6. Ninomiya et al. further disclose an aqueous solution containing chlorhexidine digluconate at 0.5 w/v% prepared

by the addition of sterilized water to the composition described above (col. 3, ln. 66 through col. 4, ln. 3; and col. 4, ln. 46-50).

With regard to the instantly claimed HLB and congeal point of the polyoxyethylene alkyl ether and/or polyoxyethylene alkenyl ether, Ninomiya et al. disclose polyoxyethylene alkyl/alkenyl ethers that are within the scope of the instant claims. Therefore, the polyoxyethylene alkyl/alkenyl ethers according to Ninomiya et al. inherently possess an HLB and congeal point within the limits of the instant claims. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,*562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01(I). Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, Ninomiya et al. disclose a composition comprising chlorhexidine digluconate, polyoxyethylene alkyl/alkenyl ether, ethanol, gluconic acid and water

wherein the amounts of each component are within the instantly claimed ranges and the composition is diluted with water upon washing skin.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
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